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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

GUID.619PA

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on July 10, 2006Signature Mark A. HollingsworthTyped or printed name Mark A. Hollingsworth

Application Number

101625,826

Filed

7/23/2003

First Named Inventor

Wagner

Art Unit

3738

Examiner

Prone, C.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number 38,491☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

Mark A. Hollingsworth
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July 10, 2006

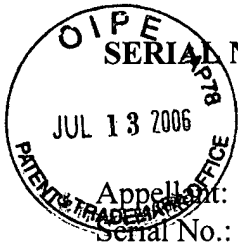
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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SERIAL NO.10/465,517

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	WAGNER et al.	Examiner:	Prone, C.
Serial No.:	10/625,826	Group Art Unit:	3738
Filed:	July 23, 2003	Docket No.:	GUID.619PA (03-521)
Title:	TUNNELING TOOL WITH SUBCUTANEOUS TRANSDERMAL ILLUMINATION		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 10, 2006.

By:

Mark A. Hollingsworth

**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections, rather than an interpretation of the claims or the prior art teachings. As such, Appellant believes this request for pre-appeal brief review is appropriate.

Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,445,608 to *Chen et al.* (hereinafter "*Chen*"). The central issue on appeal concerns whether each and every element of Appellant's claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 is found expressly or inherently in *Chen*.

In the Advisory Action dated June 8, 2006, the Examiner indicates that the "Appellant is simply arguing about intended use of the invention," and that the asserted reference, *Chen*, "clearly discloses all the claimed structural requirements and is fully capable of dissecting tissue."

Appellant respectfully submits that both of these contentions are legally and factually erroneous, and that the present rejection of the claims is improper.

Appellant's claimed subject matter is directed to a dissection tool. Each of Appellant's claims on appeal recite, in some form, a tool having a handle and an elongated dissecting member extending from the distal end of the handle. A light source or optical location indicator is disposed at the distal end of the dissecting member to provide a visual indication of a location of the dissecting member's distal end through the skin. Figure 3 of Appellant's drawings shows an embodiment of the claimed dissection tool that is used by the physician to create a subcutaneous tunnel via dissection under the skin. In a typical application, a cardiac lead is implanted within the tunnel for sensing cardiac activity and delivering cardiac electrical therapy to the heart.

Chen discloses a photodynamic treatment (PDT) probe 40 that includes an array of LEDs 54. The LEDs of probe 40 are mounted to a planar light bar 72, which is encapsulated in an electrically insulating, light diffusing semitransparent polymer 74. Probe 40 is connected to a flexible catheter 44. Figure 12A shows an example of a flexible catheter 176 contemplated by *Chen*, which is described as a PMMA or silicone rubber material (column 20, lines 13-15).

Chen clearly fails to teach a tunneling tool as contemplated in Appellant's pending claims. The combination of *Chen*'s probe and flexible catheter clearly does not constitute a dissecting member, as is recited in Appellant's claims. One skilled in the art would readily understand that the flexible catheter 44/176/262 disclosed in *Chen*, which is shown to be highly flexible so as to form a 360 degree loop in Figure 12A, would not be capable of sustaining axial loads required to dissect body tissue. There is no teaching in *Chen* that its probe and flexible catheter can be used to dissect tissue. Appellant asserts that one skilled in the art would not consider such structures to constitute a tunneling tool having a dissecting member.

Appellant's assertion that *Chen*'s probe/flexible catheter arrangement does not constitute a dissection tool is buttressed by *Chen* itself, which teaches that its implantable probe can be positioned at a treatment site only after access to the site is made possible by a surgical procedure that must be performed prior to implantation of the probe. For example, and with reference to column 8, lines 6-13, *Chen* teaches that one such surgical procedure involves making an incision that allows insertion of the implantable probe into the cardiovascular system. At column 24, lines

33-37, *Chen* teaches that a skin penetration procedure, perhaps requiring minor surgery, “is necessary to introduce and position the implantable probe at the treatment site” (*emphasis added*).

Chen does not teach that its probe can be used to create access to a treatment site. Rather, *Chen* teaches that such access must be created by another instrument that is suitable for penetrating the skin and underlying tissue. Also, the suggested use of the implantable probe within the delicate tissues of the cardiovascular system strongly suggests that the *Chen* structure can not be a dissecting tool.

Respectfully, the Examiner’s contention that Appellant’s claimed dissection tool differs from *Chen* only in terms of “intended use” is factually and legally erroneous. As is made clear in the discussion above, Appellant’s independent claims recite, in some form, a dissection member that extends from a handle. The skilled artisan, in view of Appellant’s specification or simply by drawing on common knowledge possessed by one of ordinary skill in the art, would readily understand that the flexible catheter/probe arrangement disclosed in *Chen* is clearly not a dissecting member.

The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). See, also, MPEP § 2121.01. Appellant respectfully asserts that *Chen*’s description of an implantable probe connected to (or passed through) a flexible catheter is insufficient to support the Examiner’s anticipation rejection of Appellant’s claims. It is unclear how one skilled in the art could arrive at Appellant’s claimed structure using *Chen*’s probe/flexible catheter teachings without undue experimentation.

Because *Chen* fails to disclose a dissecting member extending from a handle, *Chen* also fails to teach a light source provided at the distal end of a dissection member. Appellant further submits that it is not clear whether the light sources and arrangement of same as disclosed in *Chen* are adapted to provide a visible locating reference through the skin or dermus.

Appellant respectfully submits that recitation of a light source adapted to provide a visible locating reference through the skin or dermus is a structural feature, and not a functional feature as may be contended by the Examiner. Defining structures in terms of interrelationships or attributes they must possess has been long sanctioned in the case law. In *In re Venezia*, 530 F.2d 956, 959

(CCPA 1976), for example, the court clarified that language such as “adapted to be affixed” and “adapted to be positioned” defines structures or attributes of the element in question and limits the element to those configurations which allow for the stated interrelation of the element with other structures. *Id.*

As was previously argued, embodiments disclosed in *Chen* employ an infrared light source that is not visible to the human eye. *Chen* discourages use of visible light, since infrared light penetrates more deeply into tissue than visible light (*Chen*, column 9, lines 12-17). Further, the light source of the *Chen* devices is activated generally after the light source is placed at the treatment site within the patient, and provides local irradiation of tissue at the treatment site (*Chen*, column 11, lines 46-55). In other embodiments, the catheter itself is used as a light guide “to ensure that light is trapped within the catheter as it propagates from the proximal to the distal end of the catheter” (*Chen*, column 20, lines 13-30, *emphasis added*).

Given *Chen*’s teachings of a localized light source that is used only after the probe is positioned at the treatment site, Appellant submits that the Examiner’s contention that *Chen* teaches (expressly or inherently) a light source adapted to provide a visible locating reference through the skin is not supported by the reference teachings. Appellant notes that the experimental proof setup described in *Chen*, at column 7, lines 1-54, is a non-implanted, *in vitro* arrangement. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

To anticipate a claim, the reference must teach every element of the claim. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Appellant respectfully submits that *Chen* does not teach every element of Appellant’s rejected claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63, and therefore fails to anticipate these claims. For example, Appellant submits that *Chen* fails to teach, expressly or inherently, a dissecting member, a dissecting member extending from a handle, and a light source provided at the distal end of a dissecting member. The *Chen* device is clearly not the identical invention shown in as complete

detail as is contained in Appellant's rejected claims. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). For at least these reasons, Appellant respectfully submits that *prima facie* anticipation of Appellant's claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 has not been established.

Appellant's dependent claims 2-5, 8-11, 46, 47, 49, 50, 54-58, and 61-63, which depend from independent claims 1, 12, 29, 44, and 53 respectively, were also rejected under 35 U.S.C. §102(b) as being anticipated by *Chen*. While Appellant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with Appellant's independent claims. Therefore, dependent claims 2-5, 8-11, 46, 47, 49, 50, 54-58, and 61-63 are also not anticipated by *Chen*.

Appellant notes a mis-numbering of the original listing of claims as filed that inadvertently omitted a claim 32. Upon the indication of allowable subject matter by the Examiner, Appellant will submit an amendment to correct this omission. Alternatively, Appellant authorizes the Examiner to make such correction by way of Examiner's amendment.

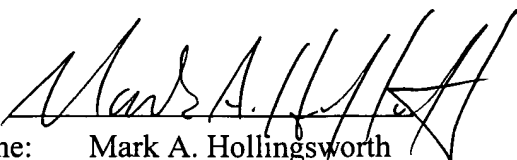
Lastly, Appellant respectfully reiterates that Appellant is entitled to consideration of the claims to additional species, including those identified by the Examiner, pursuant to 37 C.F.R. § 1.141, upon allowance of a generic claim(s). It is believed that Appellant's pending and re-joinable claims are in condition for allowance and notification to that effect is respectfully requested.

Appellant believes that this statement, when viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are clearly not proper and are without basis.

The undersigned is of record and with authority to prosecute the appeal on behalf of the Assignee.

Respectfully submitted,

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